

refills without authorization by the prescriber, and *pentobarbital sodium capsules* and *Dexedrine Spansule capsules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4-9-56. \$50 fine, sentence to imprisonment for 6 months suspended, and defendant placed on probation for 3 years.

4879. (F. D. C. No. 37221. S. Nos. 75-485/6 L, 75-564 L, 75-568/9 L.)

INFORMATION FILED: 4-5-55, E. Dist. Va., against John Charles Garland, Jr., t/a Ideal Pharmacy, Portsmouth, Va.

CHARGE: Between 5-27-54 and 6-17-54, *thyroid tablets* were dispensed once, *sulfadiazine tablets* were dispensed twice, and *Dexedrine Sulfate tablets* were dispensed twice upon requests for prescription refills without authorization by the prescriber.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before a jury on 11-14-55. On the same day, the jury returned a verdict of not guilty.

4880. (F. D. C. No. 37237. S. Nos. 60-250/1 L, 60-260 L, 60-263 L, 60-484 L, 60-559 L.)

INFORMATION FILED: 3-29-55, S. Dist. Fla., against Sanford J. Harrell (a pharmacist for Preston Drugs, Inc.), Jacksonville, Fla.

CHARGE: Between 3-7-54 and 6-2-54, *thyroid tablets* and *capsules containing a mixture of extract of ergot, apiol, and oil of savin in a vehicle of castor oil* were each dispensed once without a prescription, and *Seconal Sodium capsules* were dispensed 4 times upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 6-3-55. \$150 fine.

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PRODUCTS

	N. J. No.		N. J. No.
AM Plus capsules.....	4843	Diphetamine tablets.....	4859
Amphetamine sulfate tablets.....	4860-4874	Emmenagogue	4880
dextro-, sulfate tablets.....	4841, 4846, 4851, 4857, 4858, 4860, 4873	Ergot, apiol, and oil of savin in a vehicle of castor oil, capsules containing a mixture of.....	4880
Amytal, capsules containing.....	4854	Estrogenic substances.....	4843
Androgenic substances.....	4858, 4874	Gantrisin tablets.....	4848, 4855
Benzedrine Sulfate tablets.....	4847	Metandren Linguets.....	4858
Butazolidin tablets.....	4843	Methyltestosterone tablets.....	4874
Cortisone acetate tablets.....	4855, 4877	Nembutal Sodium capsules.....	4857, 4875, 4876
Dexedrine Spansule capsules.....	4847, 4878	Oxytocic substance.....	4880
Sulfate tablets.....	4853-4856, 4878, ¹ 4879	Penicillin tablets.....	4847, 4850-4852
Dextro-amphetamine sulfate tablets.....	4841, 4846, 4851, 4857, 4858, 4860, 4873	G troches.....	4849
		Pentids tablets.....	4843, 4847-4849

¹ (4879) Prosecution contested.

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4881-4920

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings which were terminated with the entry of default or consent decrees of condemnation and (2) injunction proceedings terminated with the entry of a consent decree of injunction. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the injunction proceedings are against the *individual* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs*.

WASHINGTON, D. C., *January 11, 1957.*

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*For omission of, or unsatisfactory, ingredients statements, see No. 4890; failure to bear a label containing an accurate statement of the quantity of the contents, No. 4890; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 4890.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS
REPORTED IN D. D. N. J. NOS. 4881-4920

Adulteration, Section 501 (a) (1), the article consisted in part of a filthy substance; Section 501 (a) (2), the article had been prepared and packed under insanitary conditions; Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia or National Formulary), and its strength differed from, and its quality fell below, the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, and its quality and purity fell below, that which it purported or was represented to possess.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, or suggested in its labeling; Section 503 (b) (4), the article was subject to Section 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505 (a), the article was a new drug within the meaning of Section 201 (p), which was introduced into interstate commerce, and an application filed pursuant to Section 505 (b) was not effective with respect to such drug.

DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED
ACCORDING TO DIRECTIONS

4881. *Hormonex*. (F. D. C. No. 38280. S. No. 30-185 M.)

QUANTITY: 233 1-oz. btls. at St. Louis, Mo.

SHIPPED: 6-15-55, from Paris, Tenn., by Golden Peacock, Inc.

LABEL IN PART: (Btl.) "Hormonex Beauty Serum Use only 8 drops daily Mitchum Distributors Fifth Ave. New York Just 8 drops of Hormonex Beauty Serum gives your skin the maximum daily allotment of natural female hormones. Use dropper top to measure 8 drops into the palm of one hand. Spread over the face and throat with the fingertips of other hand. Contains 150,000 I. U. Natural estrogenic hormones."

LIBELED: 8-15-55, E. Dist. Mo.

CHARGE: 502 (j)—the article, when shipped, was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling since the directions for use, which appeared on the bottle label, provided for the daily application of approxi-